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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,796	06/27/2003	Charles J. Doillon	14363	5886

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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,796	DOILLON ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/24/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 25-33* is/are pending in the application.

4a) Of the above claim(s) *6,7,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-15, 25, 26, and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/07/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1, 4, 25, and 26 in the reply filed on June 23, 2006 is acknowledged.

2. Applicants' cancellation of claims 16-24 in the reply filed on June 23, 2006 is acknowledged.

3. Applicants' addition of claims 28-33 in the reply filed on June 23, 2006 is acknowledged.

Election/Restrictions

4. Applicant's election with traverse of Group I (corneal implant comprising a hydrated membrane) in the reply filed on October 24, 2006 is acknowledged. The traversal is on the ground(s) that "*a search for the corneal implant defined in the claims of Group I would necessarily include a complete search of the corneal implant defined in the claims of Group II*". This is not found persuasive because the art is a crowded art, which creates a serious burden on the Examiner. It should be noted that the body of the claim does not claim any structural feature of a "corneal implant". Though Applicant asserts that examination of all pending claims would not pose an undue burden on the Examiner, such is not an accurate assertion in light of the disparate nature of the presently claimed subject matter as noted in the Requirement for Restriction of 10/11/2006.

Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore, execution of a search encompassing the entirety of Applicant's claimed subject matter would not

only constitute an undue burden on the Examiner, but consideration of the findings of such a search in accordance with the requirements of the law under 35 U.S.C. §§101,102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the classes and subclasses in which they are classified. Therefore, it is obvious that a comprehensive search of the copious amounts of patent and non-patent literature for each of the patentably distinct inventions and their permutations presently claimed would necessarily place an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 6, 7, 27, and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 24, 2006.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding claims 30 and 31, the specification does not disclose or suggest "a drug, a bioactive compound (such as: glycoproteins, adhesive peptides, etc.), or a combination thereof" as the hydration (or rehydration) solution. The specification discloses using "sterile buffered solution" (well known in the art) as the hydration solution.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4, 8-10, and 29-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Takezawa et al. (EP 0 387 975; previously cited by the Examiner in PTO-892).

Takezawa et al. disclose a hydrated (throughout the mixture of chemical compounds, there is at least one step of hydration; in addition, see page 11, lines 15-20) membrane/substrate (see page 6, lines 48-50) applicable for prostheses/implants (see page 2, lines 15-19), wherein said hydrated membrane comprises a mixture of a biological polymer (e.g., collagen) and a polyacrylamide (e.g., PNIPAAm). See page 5, lines 21-60; page 10, line 50 to page 12, line 2 (including TABLE VI). The membrane/substrate further comprises a chemical crosslink (see

page 7, lines 5-11). The claimed biological polymer:polyacrylamide ratio is shown in page 12, lines 1-2 (including TABLE VI). The membrane/substrate may comprise a bioactive compound.

With regards to claim 29, since Takezawa et al. disclose a membrane/substrate comprising the same mixture as Applicants' AND having the same biological polymer:polyacrylamide ratio, it is inherent it will have similar values for the claimed physical properties (i.e., elastic modulus of less than 10 MPA, etc.).

The recitation "corneal implant" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robei*, 88 USPQ 478 (CCPA 1951).

10. Claims 1, 2, 4, 10, 25, 26, and 30-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Meijs et al. (US 5,994,133; cited in Applicants' IDS).

Meijs et al. disclose a corneal implant (see Abstract; see column 9, lines 19-56) comprising a hydrated (throughout the mixture of chemical compounds, there is at least one step of hydration; in addition, see Example 3 and Example 7) membrane, said hydrated membrane comprising a mixture of a biological polymer (e.g., collagen, fibronectin, laminin, etc.; see column 6, lines 25-27; column 9, lines 1-5) and a polymer of an acrylamide (e.g., polyacrylamide; see column 7, line 49 to column 8, line 33). The matrix/membrane is disclosed as further comprising a chemical crosslink (see column 8, lines 34-48). The corneal implant is disclosed as applied to a human being. The membrane may comprise a bioactive compound.

11. Claims 1, 4, 10, 15, 25, 26, 30-33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chudzik et al. (US 6,410,044 B1).

Chudzik et al. disclose a corneal implant (see column 5, lines 15-27) comprising a hydrated (throughout the mixture of chemical compounds, there is at least one step of hydration; in addition, see column 7, lines 46-49) membrane, said hydrated membrane comprising a mixture of a biological polymer (e.g., gelatin, collagen, fibronectin, laminin, elastin, etc.; see column 7, lines 55-63) and a polymer of an acrylamide (e.g., polyacrylamide; see entire document). The matrix/membrane is disclosed as further comprising a chemical crosslink. Since the matrix/membrane is added to a prosthesis (e.g., corneal implant), the entire article/device comprises at least two layers (i.e., matrix/membrane + corneal implant; together forming a corneal implant). The corneal implant is intended to be applied to a human being. The membrane may comprise a bioactive compound.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 5, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. (US 5,994,133; cited in Applicants' IDS) in view of Perez et al. (WO 94/17851 A1; previously cited by the Examiner in PTO-892).

Meijs et al. disclose the invention as claimed except for particularly disclosing the use of telocollagen or atelocollagen, and the claimed membrane thickness. However, this is already known in the art. For example, Perez et al. disclose a corneal implant comprising a membrane (i.e., film or layer: see Abstract; see page 8, lines 16-18; page 12, lines 34-37), said membrane comprising a biological polymer (e.g. collagen type I, modified forms of collagen, glycosaminoglycans: see Abstract; page 13, lines 18-36; claims 1-5) and a hydrogel (e.g., polyacrylamide: see Abstract; page 11, lines 8-12; claims 1-5) having a biological polymer to polyacrylamide ratio as disclosed at page 11, lines 31-32 and having a membrane thickness as disclosed at page 11, lines 32-34, and page 12, lines 34-37 in order to provide "a suitable substrate for corneal epithelial cell growth while maintaining the desirable characteristics of hydrogels, i.e., clarity, flexibility, and ability to allow diffusive flow of materials" (see Abstract; page 7, lines 26-37; page 8, lines 20-24). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a corneal prosthesis comprising collagen type I or modified forms of collagen, and a membrane thickness of about 50 microns to about 100 microns, as taught by Perez et al., with the corneal implant of Meijs et al., in order to provide a suitable substrate for corneal epithelial cell growth while maintaining the desirable characteristics of hydrogels, i.e., clarity, flexibility, and ability to allow diffusive flow of materials.

14. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. (US 5,994,133; cited in Applicants' IDS) in view of Graham et al. (US 5,433,745; cited in Applicants' IDS).

Meijs et al. disclose the invention as claimed except for particularly disclosing the particular cross-linking agents disclosed in claims 11 and 12. However, this is already known in the art. For example, Graham et al. disclose a corneal implant comprising a membrane (i.e., film, coat, or layer), wherein said membrane comprising a biological polymer (e.g. coating of a cytophilic component such as collagen, fibronectin, etc: see column 5, lines 11-35; column 10, lines 39-43) and a hydrogel (e.g., polyacrylamide: see column 3, lines 34-59), and wherein said membrane further comprises a chemical crosslink (e.g., 1-(3-dimethylaminopropyl)-3-ethyl carboddimide or EDC: see column 6, lines 46-67; TABLE 3) in order to provide a suitable substrate for corneal epithelial cell growth (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a corneal prosthesis comprising 1-(3-dimethylaminopropyl)-3-ethyl carboddimide or EDC, as taught by Graham et al., with the corneal implant of Meijs et al., in order to provide a suitable substrate for corneal epithelial cell growth.

15. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. (US 5,994,133; cited in Applicants' IDS) in view of Takezawa et al. (EP 0 387 975 A1; previously cited by the Examiner in PTO-892)).

Meijs et al. disclose the invention as claimed, including the use of polyacrylamides, except for particularly disclosing using poly(N-isopropylacrylamide) [i.e., PNIPAAM] as the polyacrylamide. However, this is already known in the art. For example, Takezawa et al. disclose a prosthesis (see page 2, lines 17-18) comprising a membrane/film (see page 6, lines 48-49; see claim 9) comprising a collagen-PNIPAAM conjugate (see page 5, page 11, and page 12) in order to provide a cell growth substrate having high cell density and cellular function, and having

excellent self-supporting abilities (see Abstract; see page 2, lines 3-11; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis comprising a membrane/film comprising a collagen-PNIPAAM conjugate, as taught by Takezawa et al., with the corneal implant of Meijs et al., in order to provide a cell growth substrate having high cell density and cellular function, and having excellent self-supporting abilities.

16. Claims 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. (US 5,994,133; cited in Applicants' IDS).

Meijs et al. disclose the invention as claimed. Meijs et al. did not particularly disclose the claimed values of the physical properties claimed in claim 29. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the corneal implant of Meijs et al. with a particular/specific values of physical properties since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, intraocular and/or corneal implants comprising a plurality of membranes (i.e., layers, films, laminates, etc.) are well known in the art and would have been obvious in view of a patient's condition/disease, with the ordinary practitioner having been left to select a particular number of membranes based on the intended purpose (e.g., different layers may provide (i) different refractive properties; (ii) site for epithelial cell adhesion/attachment; (iii) modifying the curvature of the cornea; etc.).

Conclusion

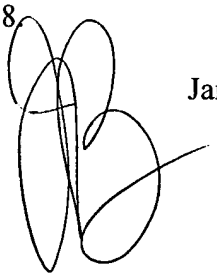
17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco



January 20, 2007

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